

REMARKS

Reconsideration of the application is respectfully requested in view of the above amendments and following remarks. Claims 1-40, 47 and 48 were pending in the present application. Claim 5 has been canceled in the present amendment. Claims 1, 3, 6, 7, and 14-17 have been amended. Claims 25-29 and 31-37 were withdrawn by the Examiner. Currently, Claims 1-4, 6-40, 47 and 48 are pending in the present application.

Claim 5 has been canceled to comply with the restriction requirement. Claim 5 defines R⁴; however, due to the Examiner's restriction requirement, m is 0, so there are no R⁴ substituents in Claim 1.

Claim 1 has been amended to delete R² is heteroaryl, s is 0 and 2, and m is 1, 2, 3 and 4 to comply with the restriction requirement. Claim 1 has been further amended to define X as a heteroaryl selected from pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl.

Claim 3 has been amended to delete "or thienyl" to comply with the restriction requirement.

Claims 6 and 7 have been amended to define X as a heteroaryl selected from pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl.

Claim 14 has been amended to delete R² is "or thienyl", s is 0 and 2, and m is 1, 2, 3 and 4 to comply with the restriction requirement. Claim 14 has been further amended define X as a heteroaryl selected from pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl.

Claim 15 has been amended to delete s is 0 and 2, and m is 1, 2, 3 and 4 to comply with the restriction requirement. Claim 15 has been further amended to define X as a heteroaryl selected from pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl.

Claim 16 has been amended to delete R² is heteroaryl, s is 0 and 2, and m is 1, 2, 3 and 4, and rewritten as a dependent claim depending from Claim 1 to comply with the restriction requirement.

Claim 17 has been amended to delete s is 0 and 2, and m is 1, 2, 3 and 4 to comply with the restriction requirement.

No new matter has been added to the above-captioned application by the above amendments. Applicants reserve the right to pursue the non-elected subject matter of the claims amended to comply with the restriction requirement in a divisional application.

CLAIM OBJECTIONS

The Examiner stated that Claims 1, 3, 5, 14, 15, 16 and 17 are objected to as being drawn to non-elected subject matter; that Claims 2-15, 17-24, 30, 38-40 and 47-48 are objected to as being dependent on a rejected base claim; and that Claim 16 is objected to because it is an independent claim.

Claim 5 has been canceled to comply with the restriction requirement. Claim 5 defines R⁴; however, due to the Examiner's restriction requirement, m is 0, and there are no R⁴ substituents in Claim 1. Applicants reserve the right to pursue the non-elected subject matter of Claim 5 in a divisional application.

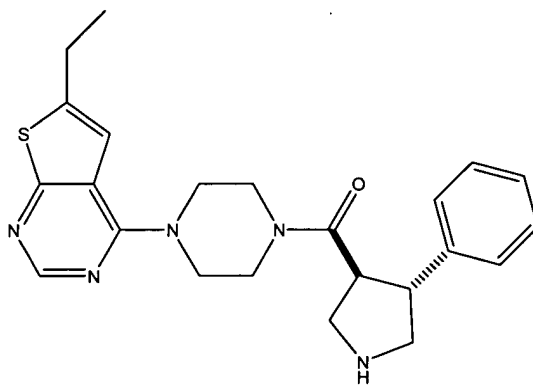
Claim 1 has been amended to delete R² is heteroaryl, s is 0 and 2, and m is 1, 2, 3 and 4. Claim 3 has been amended to delete "or thienyl." Claim 14 has been amended to delete R² is "or thienyl", s is 0 and 2, and m is 1, 2, 3 and 4. Claim 15 has been amended to delete s is 0 and 2, and m is 1, 2, 3 and 4. Claim 16 has been amended to delete R² is heteroaryl, s is 0 and 2, and m is 1, 2, 3 and 4, and rewritten as a dependent claim depending from Claim 1. Claim 17 has been amended to delete s is 0 and 2, and m is 1, 2, 3 and 4. These amendments were made to comply with the Examiner's restriction requirement. Applicants reserve the right to pursue the non-elected subject matter of Claims 1, 3, 14, 15, 16 and 17 in a divisional application.

Claims 2-15, 17-24, 30, 38-40, 47 and 48 depend directly from Claim 1, or depend from a claim that depends from Claim 1, and incorporate the amendments to Claim 1.

In view of the above amendments, Applicants respectfully request that the objection of Claims 1-24, 30, 38-40, 47-48 be withdrawn.

REJECTION UNDER 35 U.S.C. 102(e)
FOR LACK OF NOVELTY

Claims 1-4, 6-7, 11, 14, 15 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Levy et al. (US2003/0152556). The Examiner stated that Levy discloses the following compound on page 134, as Example 434:



and pharmaceutically acceptable salts, hydrates, isomers, and pharmaceutical compositions thereof.

Applicants submit that the compounds disclosed by Levy in US2003/0152556, including Example 434, do not anticipate the presently amended claims. Applicants have amended Claims 1, 6, 7, 14 and 15 to define X as a heteroaryl selected from the group consisting of: pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl. Claims 2-4, 11, and 30 depend from Claim 1, or depend from a claim that depends from Claim 1, and incorporate the amendment to Claim 1.

Applicants submit that the Levy compounds, including Example 434, are not within the scope of amended Claims 1, 6, 7, 14 and 15 of the present application, or within the scope of the claims that depend from amended Claims 1, 6, 7, 14 and 15. Levy discloses and claims compounds with a fused 5- and 6-membered bicyclic ring system, salts and compositions thereof. The definition of heteroaryl in substituent X in the presently amended claims does not include fused 5- and 6-membered bicyclic ring systems.

Applicants further submit that Levy et al. does not teach or suggest the compounds claimed in the presently amended claims, in which the X is a monocyclic heteroaryl, or a bicyclic heteroaryl that is not a fused 5- and 6- membered bicyclic ring system. As a result, the instantly claimed compounds are distinguished from Example 434 of Levy. As presently amended, the claimed compounds of formula I of

the present application are not taught or suggested by Example 434 of Levy, or a salt or composition thereof.

Applicants also submit that Levy et al. does not teach or suggest the composition presently claimed in Claim 30. The compositions disclosed by Levy in paragraphs [0074],[0075], [0076], [0078] and [0079] on pages 14 and 15 of US2003/0152556 refer to pharmaceutical compositions of the compounds of formula I of US2003/0152556. The compounds of formula I of US2003/0152556 are outside of the scope of the presently amended claims. Claim 30, which is directed to pharmaceutical compositions of the compounds of presently amended Claim 1, incorporates the amendment to Claim 1. As a result, the compositions disclosed by Levy do not anticipate the compositions claimed in Claim 30 of the present application, and the compositions disclosed by Levy are outside of the scope of the compositions claimed in Claim 30 of the present application.

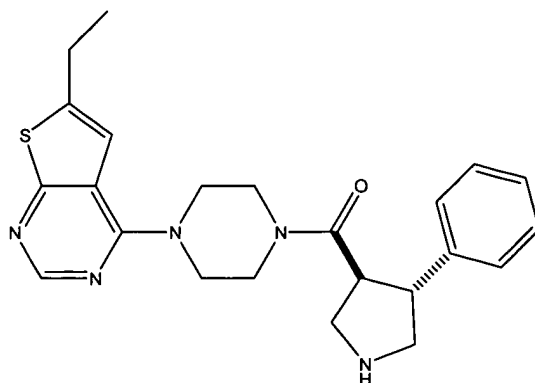
Finally, Applicants submit that the uses of the compositions disclosed by Levy do not anticipate the uses of the compositions claimed in Claim 30, which are useful to prevent and treat diseases involving the melanocortin 4 receptor, such as obesity, diabetes and sexual dysfunction. Paragraph [0078] of Levy states that the invention relates to pharmaceutical compositions and salts for preventing and treating thrombosis, and that preferred compositions contain a compound of formula I, or a salt thereof, in an amount effective to inhibit platelet aggregation, more preferably ADP-dependent platelet aggregation. Applicants submit that the use of the compositions disclosed by Levy in US2003/0152556, do not anticipate the method of treatment claims and uses of the compounds and compositions of the present application.

In view of the amendments, Applicants respectfully request that the rejection of claims 1-4, 6-7, 11, 14, 15 and 30 under 35 USC § 102(e) be withdrawn.

REJECTION UNDER 35 U.S.C. 103(a)

FOR OBVIOUSNESS

Claims 38-40 were rejected as being unpatentable over US2003/0152556. The Examiner stated that Levy et al (US 2003/0153556) discloses pharmaceutically acceptable salts, hydrates, isomers, and pharmaceutical compositions of the compound shown in Example 434 on page 134:



and in paragraphs [0078], [0075], [0076], [0078], and [0079] of pages 14 and 15 of US2003/0152556. The Examiner also stated that one of ordinary skill in the art, a pharmaceutical chemist, would produce the most stable compounds for pharmaceutical use; that the prior art claims the compounds plus pharmaceutically acceptable salts, hydrates and isomers thereof; and that one of ordinary skill in the art would be motivated to produce the salts of the instant application by reading the disclosure found in the art.

Claim 38 of the presently amended claim set claims the compound of Claim 1, wherein the pharmaceutically acceptable salt is a hydrochloride salt. Claim 39 of the present claim set claims the compound of Claim 1 wherein the pharmaceutically acceptable salt is a trifluoroacetic acid salt. Claim 40 of the present claim set claims the compound of Claim 1 wherein the pharmaceutically acceptable salt is a bis phosphate salt.

Applicants respectfully traverse the Examiner's rejection of Claim 38-40 as obvious over Levy et al. Applicants respectfully submit that the compounds of the amended claims, their salts and their uses are not prima facie obvious because Levy et al. does not teach or suggest the compounds, salts or uses claimed in the presently amended claims.

Applicants have amended Claim 1 to define X as a heteroaryl is selected from the group consisting of: pyridinyl, furyl, thienyl, pyrrolyl, oxazolyl, thiazolyl, triazolyl, triazinyl, tetrazolyl, thiadiazolyl, imidazolyl, pyrazolyl, isoxazolyl, isothiazolyl, oxathiazolyl, pyrimidinyl, pyrazinyl, pyridazinyl, quinolyl, and isoquinolyl. Claims 38, 39 and 40 of the present application depend directly from Claim 1 and incorporate the amendments to Claim 1.

There is no teaching, suggestion or motivation to make the compounds of the presently amended claims, or salts thereof, based on the disclosures of Levy. Applicants submit that the prior art does not claim the compounds of the presently amended claims, or salts thereof. The compounds disclosed in Levy, including Example 434, are not within the scope of amended Claims 1, 6, 7, 14 and 15 of the present application, or within the scope of the claims that depend from amended Claims 1, 6, 7, 14 and 15. Levy discloses and claims compounds with a fused 5-and 6-membered bicyclic ring system. The definition of heteroaryl in substituent X in the presently amended claims does not include fused 5-and 6-membered bicyclic ring systems. Applicants further submit that Levy et al. does not teach or suggest the compounds in the presently amended claims, in which the X is a monocyclic heteroaryl, or a bicyclic heteroaryl that is not a fused 5-and 6- membered bicyclic ring system. As a result, the instantly claimed compounds are distinguished from Example 434 of Levy. As presently amended, the claimed compounds of the present application are not taught or suggested by Example 434 of Levy et al. Therefore, Applicants submit that compounds of the presently amended claims are not prima facie obvious.

Applicants also submit that Levy does not teach suggest, or motivate one of ordinary skill in the art to make or use the salts claimed in Claim 38-40 of the presently amended claims. In paragraphs [0078], [0075], [0076], [0078], and [0079] of pages 14 and 15 of US2003/0152556, Levy discloses that the compounds of formula I of US2003/0152556 may be further treated to form pharmaceutically acceptable salts. However, Levy does not teach or suggest any specific pharmaceutically acceptable salt of the compounds of formula I, or any acid or bases that may be used to form acceptable pharmaceutical salts of the compounds of formula I.

Applicants further submit that there is not teaching, suggestion or motivation in Levy to one of ordinary skill in the art to make hydrochloride, trifluoroacetic acid or bis phosphate salts of the compounds of formula I of US2003/0152556. Applicants further submit that there is not teaching, suggestion or motivation in Levy to one of ordinary skill in the art to make hydrochloride, trifluoroacetic acid or bis phosphate salts of the compounds claimed in the presently amended claims. The hydrochloride, trifluoroacetic acid or bis phosphate salts of Claims 38, 39 and 40 in the presently amended claims are not taught or suggested by Levy. Furthermore, the art does not teach or suggest the most stable salts of the compounds claimed in the presently amended claims, and there is no teaching, suggestion or motivation in the art to make the hydrochloride, trifluoroacetic acid or bis phosphate salts of the compounds claimed in the presently amended claims. Therefore, Applicants submit that Claims 38, 39 and 40 of the presently amended claims are not prima facie obvious.

Finally, Applicants submit that Levy does not teach suggest, or motivate one of ordinary skill in the art to use the salts of the presently amended claims. Paragraph [0078] of Levy states that preferred compositions contain a compound of formula I, or a salt thereof, in an amount effective to inhibit platelet aggregation, more preferably ADP-dependent platelet aggregation. Applicants submit that Levy does not teach or suggest the use of the pharmaceutically acceptable salts claimed in Claims 38, 39 and 40, which are useful to prevent and treat diseases involving the melanocortin 4 receptor, such as obesity, diabetes and sexual dysfunction. Applicants submit that Levy does not teach or suggest the expected properties of compounds of formula I, or the salts of the compounds of formula I claimed in Claims 38-40.

Applicants submit that Claims 38, 39 and 40 of the presently amended claims are not prima facie obvious. In view of the above amendment to Claim 1, Applicants respectfully request that the rejections of claims 38-40 under 35 USC § 103(a) be withdrawn.

Applicants believe that all of the objections and rejections have been overcome by amendment and/or argument, and therefore earnestly solicit an early Notice of Allowance.

Applicants request that the Examiner rejoin the withdrawn method of use claims (claims 25-29, and 33-37) and pharmaceutical composition claims (claims 31-32) commensurate in scope with the amended compound claims.

Respectfully submitted,

By



Baerbel R. Brown, Reg. No. 47,449
Attorney for Applicants
MERCK & CO., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907
Tel.: (732)594-0672

February 22, 2006